

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/306,420 05/06/99 LOCARNINI

S 2551-28

EXAMINER

NIXON & VANDERHYE PC  
1100 N GLEBE ROAD 8TH FLOOR  
ARLINGTON VA 22201

HM22/0912

MOSHER, M

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

09/12/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/306,420</b>	Applicant(s) <b>Locarnini et al</b>
	Examiner <b>Mosher</b>	Group Art Unit <b>1648</b>



Responsive to communication(s) filed on 8/1/00

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-22 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

Art Unit: 1648

***Election/Restriction***

This case was not filed under the provisions of 35 U.S.C. 371, so restriction is required according to U.S. National practice. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 4-9, 13, 17, drawn to Polymerase variant virus, classified in class 435, subclass 325.1.
- II. Claims 2, 4, 10, 15, 17, drawn to Surface component variant virus, classified in class 435, subclass 325.1.
- III. Claims 3, 4-9, 10, 11, 14, 16, 17, 18 drawn to variant virus with amino acid change to two overlapping products, classified in class 435, subclass 325.1.
- IV. Claims 19, 22, drawn to method for detecting polymerase mutation, class 435, subclass 5.
- V. Claim 20, drawn to method for detecting surface antigen mutation classified, in class 435, subclass 5.

Claims 12 and 21 are not included in any group, because these claims were so unclear as to make it impossible to determine which protein is intended in these claims.

Inventions 1-III are related as combination (III) and subcombinations (I and II).

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

Art Unit: 1648

case, the combination as claimed does not require the particulars of the subcombinations as claimed because the broadest claims encompass variation in other overlapping regions of the virus genome, for example overlap of the C-terminal C region with the N-terminal Pol region, or overlap of the C-terminal Pol region with the N-terminal X region. The subcombination has separate utility, for example diagnosis of a viral variant with mutations in pol which do not affect the amino acid sequence in an overlapping open reading frame.

Inventions I and II are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I has separate utility such as diagnosis of pol mutations which do not affect surface antigen. See MPEP § 806.05(d).

Inventions I and IV are related as product and method of analyzing the product. The virus, as claimed, can be studied or detected by a materially different method, such as by detecting nucleoside treatment escape mutants.

Inventions II and V are related as product and method of analyzing the product. The virus, as claimed, can be studied or detected by a materially different method, such as by detecting neutralizing antibody escape mutants.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, divergent subject matter, and divergent search requirements, restriction for examination purposes as indicated is proper.

Art Unit: 1648

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday - Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 11, 2000

*Mary Mosher*  
MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1600

1600